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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,801	01/12/2001	Todd Elliott Piper	1363	2815

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PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/04/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,801

Applicant(s)

PIPER, TODD ELLIOTT

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. A copy of European Patent Application 160390 has not been provided.

Claim Objections

2. Claims 8 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 8 has been interpreted as if the recitation "the inbred maize plant of claim 2" read --the plant of inbred line PH54M--. Claim 27 has been interpreted as if "the inbred maize plant of claim 21" read --the maize plant having all the morphological and physiological characteristics of inbred line PH54M--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "PH54M" in claims 1, 6, 12, 14, 21, 25, 31, 33, 37, 40-42, and 44-46 render the claims and those dependent thereon indefinite. Since the name "PH54M" is not

known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "PH54M" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Amending claims 1, 6, 21, 25, 37, and 40 to recite the ATCC deposit number in which seed of corn inbred line PH54M has been deposited would overcome the rejection.

Regarding claims 3 and 22, the recitation "wherein said plant is male sterile" renders the claim indefinite. It is not clear if the claim is directed towards detasseled plants, or plants that have been transformed with a gene conferring male sterility. Claims 3 and 22 also appear to broaden the scope of their parent claims. The parent claims are drawn to plants or seeds with a defined number of traits, and claims 3 and 22 add more traits. The following amendments are suggested: 1) in claims 3 and 22, replace "male sterile" with --detasseled--; 2) add a new claim 50 directed towards a method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 with a nucleic acid that confers male sterility, and a new claim 51 directed towards a male-sterile maize plant produced by the method of claim 50.

In claim 5 and 24: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 4 or 23.

In claims 14, 33, 41, 45, and 46: the terms “high” and “above average” are relative terms that have no definite meaning. The terms do not reasonably apprise one of the scope of the invention.

In claims 16 and 35: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the corn plant breeding program of claims 15 and 34, respectively. However, claims 15 and 34 are directed to methods, not programs. It is suggested that the recitation “corn plant breeding program” in line 1 of claims 16 and 35 be replaced with --method--.

In claims 19, 20, 48, and 49: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the single gene conversion(s) of claims 18 or 47. However, claims 18 and 47 are directed to maize plants.

In claim 40: the claim is indefinite because the recitation “comprising” in line 1 does not clearly indicate how many crosses are to be performed by the method. It is suggested that the recitation --F1 hybrid-- be inserted in claim 37, line 4 after “progeny”, and in line 5 after “said”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9-20, 28-39, 41-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH54M; any F₁ hybrid corn seed produced by crossing corn plant PH54M with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH54M and expresses a combination of at least two PH54M traits; any PH54M-derived corn plant produced by crossing PH54M with any other corn plant from 0-5 times; or the corn plant grown from PH54M seed, wherein the plant has been transformed so that its genetic material contains or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH54M plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH54M is a source of breeding material; any PH54M plant that further comprises any single gene conversion(s); a process for producing inbred line PH54M comprising planting a collection of PH54M hybrid seed and PH54M itself; a method of producing PH54M-derived plant comprising crossing PH54M with another maize plant.

The specification describes morphological and physiological traits of an inbred corn plant arbitrarily designated "PH54M" (page 17, lines 3-21, Table 1 on pages 18-20; page 36, line 1 to page 37, line 12; Tables 2A-2C and 3A-3D on pages 39-45). The specification also indicates that hybrid plants were produced by crossing PH54M to an inbred corn plant designated PH7JB.

Numerous traits of the PH54M/PH7JB hybrid were compared to other hybrid plants produced by crosses of other inbred corn plants (page 37, line 15 to page 38, line 25; Tables 4A-4G, pages 46-56). The specification further indicates that upon allowance of any claims, all restrictions on the availability to a deposit of 2500 seeds of PH54M with the American Type Culture Collection will be irrevocably removed and all requirements of 37 CFR 1.801-1.809 will be met (page 57).

However, the specification also does not describe the plants produced by the corn breeding programs, transgenic PH54M plants, PH54M plants comprising single gene conversion(s), or by crosses wherein at least one ancestor is corn variety PH54M, other than PH54M/PH7JB. The morphological and physiological traits of the corn plants that are crossed with PH54M, and with progeny of that cross, are unknown, and the description of progeny and descendents of corn plant PH54M are unknown. The description of corn plant PH54M is not indicative of the description of plants and seed produced by the breeding programs and crosses, or of any of its descendents. The claimed invention also encompasses plants that express at least two of the "PH54M traits" listed in claims 14, 33, 41, 45, and 46. However, to say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by PH54M. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant PH54M. For example, Loisel et al. (U. S. Patent No. 5,986,185) describes a corn plant, designated "PH24D," which has at least two traits in common with PH54M, high grain yield, above average resistance to Northern Leaf Blight, and being adapted to the Northcentral region of the United States, for example (col. 10, lines 52-67; Table 1). The instantly claimed corn

Art Unit: 1638

plants could have PH24D as an ancestor, as well as PH54M, in which case the high grain yield, resistance to Northern Leaf Blight, and adaptability to the Northcentral region traits, for example, could have been inherited from PH24D. The claims also encompass plants that do not have to express any of the traits that are expressed by PH54M. The specification does not describe any of the traits of such plants, and the morphological and physiological description of PH54M is not indicative of the description of such plants. The description of the PH54M/PH7JB hybrid also does not provide any information concerning the description of any other hybrids. The morphological and physiological traits of PH54M/PH7JB are not indicative of the traits expressed by other hybrids. The descriptions of PH54M and PH54M/PH7JB are also not indicative of any transgenic plant or PH54M plants comprising single gene conversion(s). Further, the single genes that govern the traits contemplated in the specification at page 21, lines 20-23 are not described. Transgenes may also be of any gene, including those that effect more than one trait. The morphological and physiological characteristics of any such plant are not described. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from PH54M, which are not described. It is suggested that claims 11 and 30 be amended to list the types of transgenes contemplated in the specification, for example disease or pest resistance genes, provided the prior art teaches those isolated genes. Given the breadth of the claims encompassing corn plant PH54M having male sterility, corn plants expressing at least two traits that are also expressed by PH54M, or any trait, and descendents of PH54M, and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

5. Claims 18-20 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards maize plant PH54M, or a maize plant having all the morphological and physiological characteristics of PH54, further comprising one or more single gene conversions.

The specification teaches that single gene conversions, or introgression, of the disclosed maize plant through traditional breeding is contemplated (page 20, lines 15-30). However, the specification does not teach any PH54M plants comprising single gene conversions. It is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in

nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

6. Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH54M, or a corn plant having all the morphological and physiological characteristics of corn plant PH54M; or wherein said plants are male sterile; tissue culture of regenerable cells from said plants; a maize plant regenerated from said tissue culture capable of expression all the morphological and physiological characteristics of PH54M; method for producing a F₁ hybrid maize seed comprising crossing PH54M with a different inbred maize plant; any F₁ hybrid corn seed produced by crossing corn plant PH54M with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant

wherein at least one ancestor is PH54M and expresses a combination of at least two PH54M traits; any PH54M-derived corn plant produced by crossing PH54M with any other corn plant from 0-5 times; or the corn plant grown from PH54M seed, wherein the plant has been transformed so that its genetic material contains or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH54M plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH54M is a source of breeding material; any PH54M plant that further comprises any single gene conversion(s); a process for producing inbred line PH54M comprising planting a collection of PH54M hybrid seed and PH54M itself; a method of producing PH54M-derived plant comprising crossing PH54M with another maize plant, or wherein said method further comprises plant tissue culture methods.

Since the claimed seed of maize inbred line PH54M is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public.

If the seeds are deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit

Art Unit: 1638

requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Loisel et al. (U.S. Patent No. 5,986,185).

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH54M, or a corn plant having all the morphological and physiological characteristics of corn plant PH54M; or wherein said plants are male sterile; tissue culture of regenerable cells from said plants; a maize plant regenerated from said tissue culture capable of expression all the morphological and physiological characteristics of PH54M; method for producing a F₁ hybrid maize seed comprising crossing PH54M with a different inbred maize plant; any F₁ hybrid corn seed produced by crossing corn plant PH54M with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH54M and expresses a combination of at least two PH54M traits; any PH54M-derived corn plant produced by crossing PH54M with any other corn plant from 0-5 times; or the corn plant grown from PH54M seed, wherein the plant has been transformed so that its genetic material contains or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH54M plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH54M is a source of breeding material; any PH54M plant that further comprises any single gene conversion(s); a process for producing inbred line PH54M comprising planting a collection of PH54M hybrid

Art Unit: 1638

seed and PH54M itself; a method of producing PH54M-derived plant comprising crossing PH54M with another maize plant, or wherein said method further comprises plant tissue culture methods.

Loisel et al. teaches seed of an inbred maize line designated "PH24D," plants produced by growing said seed, and plants and plant parts having all of the physiological and morphological characteristics of PH24D (col. 10, lines 52-67; Table 1; claims). It appears that the claimed plants and seeds of the instant invention may be the same as PH24D, given that they exhibit similar traits, high grain yield, above average resistance to Northern Leaf Blight, and being adapted to the Northcentral region of the United States, for example (col. 10, lines 59-67; Table 1). Alternatively, if the claimed plants, plant parts, and seeds of PH54M are not identical to PH24D, then it appears that PH24D only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH54M. Loisel et al. also teach methods to confer male sterility and plant PH24D where it is further male sterile; production of tissue culture of regenerable cells from a plant of line PH24D, wherein regenerable cells are from tissues including flowers, pollen, ovules, among others; a plant produced from tissue culture of PH24D that is capable of expressing all of the morphological and physiological traits of PH24D; methods for producing hybrid seeds and plants wherein a plant of inbred line PH24D is crossed with another inbred corn plant, and the ensuing seed are harvested, or wherein the method further comprises utilizing plant tissue culture methods to derive progeny; corn plant breeding programs, including backcrossing, pedigree breeding, recurrent selection, among

Art Unit: 1638

others; method for producing PH24D inbreds comprising planting a collection of seed of PH24D and a hybrid, one of whose parents is PH24D, and identifying inbred PH24D by decreased vigor or identifying seed or the inbred plants with homozygous genotype; PH24D comprising transgenes operably linked to regulatory elements, introduced via genetic engineering or breeding, as well as crossing the transformed plant with another plant to produce progeny comprising the inherited transgene; and crossing two corn plants wherein either one or both parents is PH24D, and crossing the resultant plant with itself or another corn plant to derive further progeny, and repeating such crossing 0 to 5 times; and an F₁ hybrid produced by crossing PH24D with inbred PH2KN (col. 2, line 4 to col. 5, line 11; col. 15, line 25 to col. 28, line 67; claims). Note that the plants produced by crossing a transformed PH24D plant with a non-transformed PH24D plant produced a PH24D plant with single gene conversions. The claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Loisel et al.

8. No claim is allowed.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and


Application/Control Number: 09/759,801

Page 15

Art Unit: 1638

703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

September 2, 2002


ASHWIN D. MEHTA, PH.D.
PATENT EXAMINER